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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,707

01/19/2007

Osamu Ohara

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KILYK & BOWERSOX, P.L.L.C.

400 HOLIDAY COURT

SUITE 102

WARRENTON, VA 20186

EXAMINER

KIM, ALEXANDER D

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,707	<b>Applicant(s)</b> OHARA ET AL.	
	<b>Examiner</b> ALEXANDER D. KIM	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. The Examiner acknowledges Applicants' election of Group I in the response filed on 2/20/2008. However, the previous Requirement for Restriction/Election mailed out on 1/22/2008 did not treat the instant application as a 371 of PCT/JP05/05918. Upon re-evaluation of the claims, It became apparent that the polynucleotide SEQ ID NO: 3 and 5 in Claims 2 and 3 (respectively) are fragments of SEQ ID NO: 1. Claim 21 was included in the Group I inadvertently, wherein Claim 21 is drawn to an agent comprising a compound that inhibits the expression of the polynucleotide which is not a polynucleotide itself. Thus, the previous Requirement for Restriction/Election is vacated. The instant office action is a new restriction/election requirement.

2. By virtue of a preliminary amendment filed on 09/28/2006, claims 4-5, 6-7, 12-13, 14-15, 17 and 19-23 have been amended. Claims 1-23 are pending in the instant case.

### ***Restriction***

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-9 and 23, drawn to a polynucleotide shown by the nucleotide sequence set forth in SEQ ID NO: 1, 3, 5; their complementary nucleotide sequences; a polynucleotide encoding a protein shown by the amino acid sequence set forth in SEQ ID NO: 2, 4, 6; their complementary nucleotide sequences; a kit and comprising said polynucleotide.
- II. Claims 10-12 and 23, drawn to a protein shown by the amino acid sequence set forth in SEQ ID NO: 2, 4 or 6; and a kit comprising said polypeptide.
- III. Claim 13, drawn to a method of producing the protein shown by the amino acid sequence set forth in SEQ ID NO: 2.
- IV. Claims 14, 21 and 23, drawn to an antibody that recognizes the protein according to the amino acid sequence set forth in SEQ ID NO: 2; an agent comprising said antibody for preventing and/or treating a stomach cancer; and a kit containing said antibody thereof.
- V. Claims 15-18, drawn to a method of identifying a compound that inhibits the function of the protein according to Claim 10 and/or the expression of the polynucleotide or a complement thereof, comprising: detecting and determining the compound inhibits the function of the protein and/or the expression of the polynucleotide detection an usage of protein according to Claim 10; or using a protein, a polynucleotide encoding a protein of SEQ ID NO: 2, wherein the method does not involves antibody.

- VI. Claims 17-18, drawn to a method of identifying a compound that inhibits the function of the protein according to Claim 10 and/or the expression of the polynucleotide or a complement thereof, comprising using an antibody.
- VII. Claims 19-20, drawn to a method of determining whether a tissue specimen derived from a human stomach tissue, which is a tissue derived from a human stomach tumor or not comprising measuring an amount of expression of the polynucleotide.
- VIII. Claim 21, drawn to an agent for preventing and/or treating a stomach tumor comprising a compound that inhibits the function of the protein and/or the expression of the polynucleotide.
- IX. Claim 22, drawn to a method of preventing and/or treating a stomach tumor comprising using a compound.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I, a first product, requires as its special technical feature of a polynucleotide shown by the nucleotide sequence set forth in SEQ ID NO: 1. However, this special technical feature is not required by the Groups II-IX. Group I is drawn to a polynucleotide. Group II is drawn to a protein. Group III is drawn to a method of producing a protein. Group IV is drawn to an antibody that recognizes a protein. Group V is drawn to a method of identifying a compound that inhibits the

function of the protein according to Claim 10 and/or the expression of the polynucleotide. Group VI is drawn to a method of identifying a compound that inhibits the function of the protein according to Claim 10 and/or the expression of the polynucleotide or a complement thereof. Group VII is drawn to a method of determining whether a tissue specimen derived from a human stomach tissue. Group VIII is drawn to an agent for preventing and/or treating a stomach tumor comprising a compound that inhibits the function of the protein and/or the expression of the polynucleotide. Group IX is drawn to a method of preventing and/or treating a stomach tumor comprising using a compound. Therefore, Groups II-IX do not share the special technical feature of polynucleotide SEQ ID NO: 1 and do not relate to a single general inventive concept.

#### ***Election of Species***

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In Group I, each polynucleotide (i.e., a polynucleotide encoding SEQ ID NO: 2, a polynucleotide encoding SEQ ID NO: 4 and a polynucleotide encoding SEQ ID NO: 6) in Claims 1-3 is a single species.

In Group II, each polypeptide (SEQ ID NO: 2, 4 and 6) in Claims 10-12 is a single species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Elect one polynucleotide or polypeptide sequence for a species election

The following claim(s) are generic: 4-9 in Group I.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each sequence listed above for species election are different from each other by virtue of distinct nucleotide sequence.

### ***Notice of Possible Rejoinder***

5. The examiner has required restriction between product and process claims.

Art Unit: 1652

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Election***

6. Applicant is advised that the reply to this requirement to be complete must



include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/  
Examiner, Art Unit 1656

/Richard G Hutson, Ph.D./  
Primary Examiner, Art Unit 1652